

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO**

Civil Case No. _____

Frieda Aaron, Katrina Allen, Sherri Lynn Allen (Baldrick), Rebecca Applegate, Sandy & Brad Arnold, Nicole Baker, Jennifer Ballinger, Kimberly Balzar, Randy Brewer, Cindy Bartlett, Jann Beckett, Patricia Boone, Deena Borchers, Rebecca (Becky) Breitenstain, James Brown Jr., Andrew Carr, Sherri Cinquina, Chris Clark, Jessica Cochran, Gary L. Coots, Kathryn Curley, William Dabney, Nellie Davis, Damon Deck, Sandra Dennis, Robert Densler, Kristine Dority, Carolyn Dotson, Dawn (Dooley) Dunklin, Alyssa Engle, Jacob Feltner, Karen Feltner, Christine Gerald, Gloria Greene, Jenny Grimm, Erin Gross, Dorothy Hamilton, Barbara Hensley, Jennifer Hickey, Tammy Hughes, Laura Johnson, Sarah Juergens, Valerie Kopp, Sheila Pogue-Krabacher, Patricia Legendre, Beth Leisring (Morgan), Tim Marshall, Julie Martin, Derek Mayfield (minor) by Holly Mayfield, Laura Kathleen Kranbuhl-McKee, Randall Metcalf, Sarra Mueller(minor) by Steven Moller, Joetta Nafe, Tonya Neal, Teresa Nichols, Crystal Pierce, Jeff Potts, Sandra Radeke, Samantha Redrow, Kent Reynolds II, Lisa Reynolds, John Richardson, Jason Riley, Jason Romer, Laura Jo Romito, Dorothy Rose, Josh Roy, Mike Sand, Joseph Schimmel, David Scott, Steven Andrew Schultz, Ron Schuster, Ali Scully, Brenda Shell, Greg Shott, Donna Smallwood, David Smith, David Snider, Samantha Lynn Thomas (minor), by Jim Thomas, Stephanie Herrim-Threm, Daniel Webber, Brandon Webster, Carol Wilson, Kenny Wilson, Robert Wilson, Billy Wolsing, Brett Wren, Julie Wright

Plaintiffs

CIVIL RICO COMPLAINT

JURY TRIAL DEMANDED

v.

ABUBAKAR ATIQ DURRANI, M.D.

SERVE:

Dr. Atiq Durrani
Center for Advanced Spine Technologies
4555 Lake Forest Drive, Suite 150
Cincinnati, Ohio 45254

and

**CENTER FOR ADVANCED
SPINE TECHNOLOGIES, INC.**

SERVE:

CT CORPORATION SYSTEM
1300 East Ninth Street, Suite 1010

Cleveland, Ohio 44114

and

WEST CHESTER MEDICAL CENTER, LLC.,

SERVE:

West Chester is GH&R Business Services, Inc.
511 Walnut Street, 1900 Fifth Third Center
Cincinnati, Ohio 45202

and

UC HEALTH, INC.

SERVE:

West Chester is GH&R Business Services, Inc.
511 Walnut Street, 1900 Fifth Third Center
Cincinnati, Ohio 45202

and

MEDTRONIC SOFAMOR DANEK, INC.

SERVE:

Toni Greer
2600 Sofamor Danek Dr.
Memphis, Tennessee 38132-1719

and

MEDTRONIC SOFAMOR DANEK, USA, INC.

SERVE:

Toni Greer
2600 Sofamor Danek Dr.
Memphis, Tennessee 38132-1719

and

MEDTRONIC, INC.

SERVE:

Medtronic is CT Corporation System
251 E. Ohio Street Suite 1100
Indianapolis, IN 46204.

and

CHILDREN'S MEDICAL CENTER, INC.

SERVE:

Frank C Woodside, III, 1900 Chemed Center
255 E. Fifth Street
Cincinnati, Ohio 45202.

Defendants.

Plaintiffs bring this Civil Rico Complaint and state claims the State of Ohio, by and through undersigned counsel, Eric C. Deters, and allege as follows.

SUMMARY INTRODUCTION

1. This is an action Civil Rico Complaint and state claims against Defendants Abubakar Atiq Durrani, M.D. ["Durrani"], Center for Advanced Spine Technologies, Inc. ["CAST"], West Chester Hospital, LLC. ["West Chester"], UC Health, Inc. ["UC Health"] and Medtronic Sofamar Danek USA, Inc., Medtronic Sofamar Danek Inc., and Medtronic, Inc. ["Medtronic"] and Children's Medical Center, Inc (hereafter Children's) to recover damages under Federal Civil Rico.
2. The Plaintiffs are Frieda Aaron, Katrina Allen, Sherri Lynn Allen (Baldrick), Rebecca Applegate, Sandy & Brad Arnold, Nicole Baker, Jennifer Ballinger, Kimberly Balzar, Randy Brewer, Cindy Bartlett, Jann Beckett, Patricia Boone, Deena Borchers, Rebecca (Becky) Breitenstain, James Brown Jr., Andrew Carr, Sherri Cinquina, Chris Clark, Jessica Cochran, Gary L. Coots, Kathryn Curley, William Dabney, Nellie Davis, Damon Deck, Sandra Dennis, Robert Densler, Kristine Dority, Carolyn Dotson, Dawn (Dooley) Dunklin, Alyssa Engle, Jacob Feltner, Karen Feltner, Christine Geraldts, Gloria Greene,

Jenny Grimm, Erin Gross, Dorothy Hamilton, Barbara Hensley, Jennifer Hickey, Tammy Hughes, Laura Johnson, Sarah Juergens, Valerie Kopp, Sheila Pogue-Krabacher, Patricia Legendre, Beth Leisring (Morgan), Tim Marshall, Julie Martin, Derek Mayfield (minor) by Holly Mayfield, Laura Kathleen Kranbuhl-McKee, Randall Metcalf, Sarra Mueller(minor) by Steven Moller, Joetta Nafe, Tonya Neal, Teresa Nichols, Crystal Pierce, Jeff Potts, Sandra Radeke, Samantha Redrow, Kent Reynolds II, Lisa Reynolds, John Richardson, Jason Riley, Jason Romer, Laura Jo Romito, Dorothy Rose, Josh Roy, Mike Sand, Joseph Schimmel, David Scott, Steven Andrew Schultz, Ron Schuster, Ali Scully, Brenda Shell, Greg Shott, Donna Smallwood, David Smith, David Snider, Samantha Lynn Thomas (minor), by Jim Thomas, Stephanie Herrim-Threm, Daniel Webber, Brandon Webster, Carol Wilson, Kenny Wilson, Robert Wilson, Billy Wolsing, Brett Wren, Julie Wright. More will be added as they are retained.

3. Unnecessary procedures are criminal acts. Defendants Durrani, CAST, West Chester, UC Health and Children's performed medically unnecessary, experimental spines surgeries on Plaintiffs using falsely and improperly marketed Medtronic medical devices and drugs.
4. During these unnecessary spine surgeries Defendant Durrani implanted cervical and thoracic rods, screws and cages ["hardware"] into Plaintiffs and used a drug called Infuse/BMP-2 ["BMP-2"].
5. BMP-2 is manufactured, marketed, sold and distributed by Defendant Medtronic under the trade name "Infuse". BMP-2 is not approved by the Food and Drug Administration for use on the cervical and thoracic spine. (See FDA Public Health Notification: Life Threatening Complications Associated with Recombinant Bone Morphogenetic Protein

(BMP-2) in Cervical Spine Fusion, July 1, 2008, Exhibit 1). BMP-2 is not safe nor approved for use on children less than twenty-one (21) years of age. (See Medtronic product package warnings, INFUSE/BMP-2, Exhibit 2)

6. Defendant Medtronic improperly marketed and influenced research related to the safety and efficacy of Infuse/BMP-2 both before and after the release of BMP-2 into the marketplace. (See United States Senate Committee on Finance, Staff Report on Medtronic's Influence on Infuse Clinical Studies, October 2012, S. Prt. 112-38, Exhibit 3).
7. Defendants Medtronic, Durrani and CAST knowingly and falsely marketed BMP-2 to Plaintiffs as safe and approved for use in Plaintiffs' cervical and thoracic spine surgeries. Defendants Durrani, CAST, West Chester, UC Health and Children's knowingly misled Plaintiffs concerning BMP-2 used in Plaintiffs' cervical and thoracic spine surgeries. (See Exhibits A, B and C.)
8. Defendants Durrani, CAST, West Chester, UC Health and Children's knowingly and falsely misled the government by stating a) the surgeries on were medically necessary and b) that the Defendants had obtained proper informed consent of the Plaintiffs to use the hardware and BMP-2 on Plaintiffs.
9. These unnecessary, experimental surgeries by Defendant Durrani occurred at medical facilities provided by Defendants West Chester, UC Health and Children's, in the presence of Medtronic sales representatives and with the knowledge and encouragement of Medtronic. (See Exhibits A, B and C).
10. The hardware and BMP-2 was manufactured by Defendant Medtronic, sold by Defendants Medtronic, West Chester, UC Health and Children's, marketed by

Defendants Medtronic, CAST and Durrani, and distributed by Defendants Medtronic, West Chester, UC Health, Children's and Durrani. All Defendants improperly profited from false claims paid by the government and private insurance.

11. Defendant Durrani holds the patent to the hardware and sold the rights to the hardware to Medtronic. Defendant Durrani is a paid consultant for Defendant Medtronic.
12. Medtronic paid Durrani consulting fees and other royalties in consideration for using the hardware and BMP-2 in surgeries on Plaintiffs. Furthermore, and Durrani receives improper payments and "kickbacks" when he experimentally used the drug BMP-2 and the hardware on Plaintiffs and other unsuspecting patients.
13. In summary, through the joint and several acts and omissions of these Defendants, Plaintiffs became unsuspecting experiments for the real-world testing of Medtronic hardware and BMP-2, by and through Durrani, CAST, West Chester, and UC Health who had secret financial connections to Medtronic, improper financial motives, and submitted false claims. The government paid for these improper and unregulated experiments as a result of false claims made by the Defendants under the veil of "medically necessary" surgeries.
14. The cumulative cost of the Plaintiffs' surgeries, the related follow up care, physical therapy, prescriptions, injections, and image studies that were falsely submitted to the government for payment is estimated to be approximately \$2,500,000.00 - 3,000,000.00. Plaintiffs suspect there are numerous other similarly situated persons who underwent experimental surgery by these Defendants, and who received Medtronic hardware and screws. The cumulative estimated cost to the government as a result of other false claims is hundreds of millions of dollars.

PARTIES

15. Since over one hundred patients have contacted counsel and nearly one hundred have claims, it is believed there are hundreds and hundreds more who have suffered at the hands of Dr. Durrani.
16. All listed Plaintiffs are current residents in either Kentucky or Ohio.
17. Dr. Durrani performed these surgeries at West Chester Hospital and Children's Medical Center.
18. Dr. Durrani is a member of the Center for Advanced Spine Technologies (CAST).
19. Dr. Durrani has a business relationship with Medtronic, the maker of BMP-2. This business relationship includes financial compensation which is unknown.
20. BMP-2 is a bone morphogenic protein.
21. Dr. Durrani is a native of Pakistan, the place of his birth and childhood.
22. Dr. Durrani travels to and from Pakistan, the place of his birth and childhood.
23. Dr. Durrani has told some patients he's a Prince in Pakistan.
24. Dr. Durrani maintains his family owns an international textile business which makes him independently wealthy.
25. Dr. Durrani claims ownership of a surgical tool business in Pakistan.
26. Several state and federal agencies have opened investigations into Dr. Durrani's surgical practices and his billings practices.
27. Tri-state orthopedic and neurosurgeon doctors support Plaintiffs' medical malpractice, fraud and battery claims.

28. The Plaintiffs claims involve unnecessary surgeries, improper use of metal hardware such as screws and improper and undisclosed use of BMP-2.
29. Plaintiffs are citizens of the Commonwealth of Kentucky.
30. Plaintiffs are citizens of the State of Ohio.
31. Defendant Abubakar Atiq Durrani was born in Pakistan, and frequently travels to Pakistan. Durrani is currently a licensed physician in Kentucky and Ohio, and resides in Ohio. The status of his citizenship is unknown. Defendant Durrani can be served at his business location, 6950 Burlington Pike, Florence Kentucky, or in the alternative, 4555 Lake Forest Drive, Suite 150, Cincinnati, Ohio.
32. Defendant CAST is a corporation organized under the laws of Ohio, and has business and medical offices in Kentucky and Ohio. Defendant CAST is owned, in whole or in part, by Defendant Durrani. The agent for service of process for CAST is CT Corporation , 1300 East 9th Street, Suite 1010, Cleveland, Ohio 44114.
33. Defendant West Chester Hospital, LLC is a corporation organized under the laws of Ohio, and provides medical facilities and billing support to physicians, including Durrani, in the State of Ohio. The agent for service of process for West Chester is GH&R Business Services, Inc. 511 Walnut Street,, 1900 Fifth Third Center, Cincinnati, Ohio 45202.
34. Defendant UC Health, Inc. is a corporation organized under the laws of Ohio, and provides medical facilities, management, administrative, ancillary, and billing support to physicians, including Durrani, in the State of Ohio. The agent for service of process for West Chester is GH&R Business Services, Inc. 511 Walnut Street, 1900 Fifth Third Center, Cincinnati, Ohio 45202.

35. Medtronic Sofamor Danek USA, Inc. is a corporation organized under the laws of the State of Tennessee, with its principal place of business in Memphis, Tennessee, Medtronic has sales representatives, inter alia, in Kentucky and Ohio. Medtronic sales representatives were present during the experimental surgeries performed on Realtors. The agent for service of process for Medtronic is Toni Greer, 2600 Sofamor Danek Dr, Memphis, Tennessee 38132-1719.

36. Children's Medical Center, Inc. is an Ohio corporation.

37. Plaintiffs have under 18 U.S.C. 1964(c) a private right of action since they are a "persons" who have suffered compensable injury.

JURISDICTION & VENUE

38. Plaintiffs incorporate by reference each and every previous paragraph as if fully restated herein.

39. This court has jurisdiction over this action pursuant to 18 U.S.C. §1964.

40. Venue is proper in this judicial district pursuant to 18 U.S.C. §1965 and 28 U.S.C. §1391 because Defendants are subject to personal jurisdiction in this judicial district and reside in this district.

FACTUAL ALLEGATIONS COMMON TO ALL RICO COUNTS

41. Plaintiffs incorporate by reference each and every previous paragraph as if fully restated herein. In addition, Exhibits A, B and C detail the factual basis for the Civil Rico claims.

42. Defendant Durrani is a culpable person subject to liability under the RICO statute as he is "an entity capable of holding a legal or beneficial interest in property."

43. Defendants “CAST,” Children’s, West Chester, UC Health and Medtronics are culpable persons subject to liability under the RICO statute as it is “an entity capable of holding a legal or beneficial interest in property.”

44. Defendant Durrani at all relevant times was an employee of, participant in, and associated with the other Defendants. Defendants therefore are an “enterprise” as defined by 18 U.S.C. §1961(4) as “any individual, partnership, corporation, association or other legal entity, and any union or group of individuals associated in fact although not a legal entity.”

45. The other Defendants other than Durrani, as corporations, at all relevant times were participants in and associated in the enterprise. Defendants therefore were an “enterprise” as defined by 18 U.S.C. §1961(4) as “any individual, partnership, corporation, association or other legal entity, and any union or group of individuals associated in fact although not a legal entity.”

46. Defendants an “enterprise” as previously noted under 18 U.S.C. §1961(4), has directly engaged in the production and distribution of goods and services in interstate commerce and as such has affected interstate commerce as an “enterprise”.

47. Defendants as an “enterprise” as previously noted under 18 U.S.C. §1961(4), have directly engaged in the production and distribution of goods and services in interstate commerce and as such has affected interstate commerce as an “enterprise”.

48. Defendants as an “enterprise” as previously noted under 18 U.S.C. §1961(4), have engaged in acts of racketeering activity, namely violations of 18 U.S.C. §1341 (mail fraud) and 18 U.S.C. §1343 (wire fraud).

49. Defendants as an “enterprise” as previously noted under 18 U.S.C. §1961(4), have engaged in acts of racketeering activity, namely violations of 18 U.S.C. §1341 (mail fraud) and 18 U.S.C. §1343 (wire fraud).
50. Defendants as an “enterprise” as previously noted under 18 U.S.C. §1961(4), have engaged in a pattern of racketeering activity, namely multiple violations of 18 U.S.C. §1341 (mail fraud) and 18 U.S.C. §1343 (wire fraud).
51. Defendants as an “enterprise” as previously noted under 18 U.S.C. §1961(4), have engaged in a pattern of racketeering activity, namely multiple violations of 18 U.S.C. §1341 (mail fraud) and 18 U.S.C. §1343 (wire fraud).
52. Defendants as an “enterprise” as previously noted under 18 U.S.C. §1961(4), have engaged in a pattern of racketeering activity with acts related to each other by similar purposes victims, participants and methods of commission.
53. Defendants as an “enterprise” as previously noted under 18 U.S.C. §1961(4), have engaged in a pattern of racketeering activity with acts related to each other by similar purposes victims, participants and methods of commission.
54. Defendants as an “enterprise” as previously noted under 18 U.S.C. §1961(4), have engaged in a pattern of racketeering activity that has been continuous over a substantial period of time continuing to the present.
55. Defendants as an “enterprise” as previously noted under 18 U.S.C. §1961(4), have engaged in a pattern of racketeering activity that has been continuous over a substantial period of time continuing to the present.

56. Defendants as an “enterprise” as previously noted under 18 U.S.C. §1961(4), have engaged in a pattern of racketeering activity that has been part of his regular way of doing business.
57. Defendants as an “enterprise” as previously noted under 18 U.S.C. §1961(4), have engaged in a pattern of racketeering activity that has been part of its regular way of doing business.
58. All named Plaintiffs are former patients of Durrani and Defendants and are “persons” as defined by 18 U.S.C. 1964(c) which creates a private right of action for any “person” who has suffered a compensable injury including natural persons.
59. All named Plaintiffs have sustained injury to their business or property including out-of-pocket financial losses, lost co-payments and deductibles, lost wages, lost economic opportunities, and lost fringe benefits all by reason of the Defendants previously identified pattern of racketeering activity.
60. All named Plaintiffs have sustained injury to their business or property including out-of-pocket financial losses, lost co-payments and deductibles, lost wages, lost economic opportunities, and lost fringe benefits all by reason of the Defendants previously identified pattern of racketeering activity.
61. All named Plaintiffs have sustained their injuries within the past four (4) years and thus are not barred by the applicable statute of limitations.

COUNT I (RICO §1962(c))

62. Plaintiffs incorporate by reference each and every previous paragraph as if fully restated herein.

63. Defendants as, an “enterprise” as previously noted under 18 U.S.C. §1961(4), have engaged in acts of racketeering activity, namely violations of 18 U.S.C. §1341 (mail fraud) and 18 U.S.C. §1343 (wire fraud).
64. Pursuant to 9(B) Plaintiffs base their Rico claims on a mail or wire fraud scheme with the time, place, content of, and parties to the fraudulent communications, which deceived plaintiffs by those communications described in Exhibits A, B and C.
65. Defendants as an “enterprise” as previously noted under 18 U.S.C. §1961(4), have engaged in acts of racketeering activity, namely violations of 18 U.S.C. §1341 (mail fraud) and 18 U.S.C. §1343 (wire fraud).
66. Defendants as an “enterprise” as previously noted under 18 U.S.C. §1961(4), have engaged in a pattern of racketeering activity, namely multiple violations of 18 U.S.C. §1341 (mail fraud) and 18 U.S.C. §1343 (wire fraud).
67. Defendants as an “enterprise” as previously noted under 18 U.S.C. §1961(4), have engaged in a pattern of racketeering activity, namely multiple violations of 18 U.S.C. §1341 (mail fraud) and 18 U.S.C. §1343 (wire fraud).
68. Defendants as an “enterprise” as previously noted under 18 U.S.C. §1961(4), have engaged in a pattern of racketeering activity with acts related to each other by similar purposes victims, participants and methods of commission as demonstrated by these multiple counts.
69. Defendants as an “enterprise” as previously noted under 18 U.S.C. §1961(4), have engaged in a pattern of racketeering activity with acts related to each other by similar purposes victims, participants and methods of commission as demonstrated by these multiple counts.

70. Defendants as an “enterprise” as previously noted under 18 U.S.C. §1961(4), have engaged in a pattern of racketeering activity that has been continuous over a substantial period of time continuing to the present as demonstrated by these multiple counts.
71. Defendants as an “enterprise” as previously noted under 18 U.S.C. §1961(4), have engaged in a pattern of racketeering activity that has been continuous over a substantial period of time continuing to the present as demonstrated by these multiple counts.
72. Defendants as an “enterprise” as previously noted under 18 U.S.C. §1961(4), have engaged in a pattern of racketeering activity that has been part of his regular way of doing business as demonstrated by these multiple counts.
73. Defendants as an “enterprise” as previously noted under 18 U.S.C. §1961(4), have engaged in a pattern of racketeering activity that has been part of its regular way of doing business as demonstrated by these multiple counts.
74. Plaintiffs are persons as defined by 18 U.S.C. 1964(c) which creates a private right of action for any “person” who has suffered a compensable injury including natural persons.
75. Plaintiffs have sustained injury to their business or property including out-of-pocket financial losses, lost co-payments and deductibles, lost wages, lost economic opportunities, and lost fringe benefits all by reason of Defendant Durrani’s previously identified pattern of racketeering activity.
76. As described in this Complaint, Defendants Durrani, CAST, UC Health, West Chester and Medtronic, by and through their its officers, agents, and employees, violated the False Claims Act, 31 U.S.C. §§ 3729 when they (i) knowingly presented, or caused to be presented, to the United States Government, a false or fraudulent claim for payment or approval; (ii) knowingly made, used, or caused to be made or used, a false record or

statement to get a false or fraudulent claim paid or approved by the Government; and (iii) knowingly made, used, or caused to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government.

77. "Knowingly" is defined in the False Claims Act as (1) actual knowledge, (2) deliberate ignorance of the truth or falsity of the information, or (3) reckless disregard of the truth or falsity of the information.
78. As described in this Complaint, and in the alternative, Defendants Durrani, CAST, UC Health, and West Chester Hospital and Medtronics, for the improper benefit of one or all Defendants, by and through their its officers, agents, and employees conspired to commit, and/or committed violation(s) of the False Claims Act, and other improper acts and omissions, as alleged in this Complaint.
79. Defendants alone, or in conjunction with one another, authorized and/or ratified the violations of the False Claims Act and criminal battery and other state criminal law claims committed by their various officers, agents, and employees.
80. Defendants knowingly made false billing claims, falsified medical procedures, made false statements of material fact, falsified medical records, submitted false medical billing records, and/or performed and/or cooperated in medically unnecessary surgeries in order to obtain payment from Medicare and/or obtain other improper consideration and payments from the United States.
81. Defendants preyed on Medicaid and Medicare recipients, including Plaintiffs, because of weaknesses and vulnerabilities of the governments' pre-authorization, payment, reimbursement, and utilization review processes, in contrast to commercial insurers.

82. The type of surgeries at issue herein are substantially lucrative, spine surgeries.
83. Defendants fraudulently induced Medicaid and Medicare recipients, including Plaintiffs to undergo unnecessary, experimental and/or contraindicated surgeries.
84. As an example, see Exhibits A, B and C. David Scott's is uses herein as an example. On January 25, 2010, Defendant Durrani, acting during the course and scope of his employment with Defendant CAST, performed unnecessary, improper, and/or unsafe surgery on Ralph David Scott, with full medical and facility privileges at Defendant facilities UC Health and Westchester Hospital, and thereafter these Defendants knowingly submitted false billing to Medicare in consideration for said surgery.
85. These Defendants received payments and/or other consideration, directly or indirectly, from Medicare after submitting false and deceptive claims for payment, which claims were based on false information that the surgery on January 25, 2010 was medically necessary; performed properly; with proper warnings, full disclosure, and informed consent; and included surgery at level T9-T10.
86. Defendants deceptive and false statements concerning the surgery on January 25, 2010 were the basis for Medicare payments to the Defendants.
87. The operative report of Randall Wolf, MD, the thoracic surgeon who performed the first stage of the January 25, 2010 surgery indicates the surgery team was unable to access T9-T10.
88. The report states "the fourth level disk space was not entered, despite even attempts at osteotomy of the calcified lip." Dr. Wolf's report was dictated immediately after the surgery.

89. On January 25, 2010, Dr. Wolf was employed by Defendant CAST. However, Dr. Wolf is no longer employed by Defendant CAST.

90. The Nursing intraoperative note of January 25, 2010 indicates surgery only occurred at levels T6-T9, and not T9-T10.

91. However, the Nursing implant log of January 25, 2010 indicates the implantation of 8 screws, not 6.

92. The radiology Report of January 25, 2010 indicates posterior fusion T6-T9.

93. An MRI was performed at the direction of Dr. William Tobler, MD of the Mayfield Clinic on February 7, 2013, Dr. Tobler informed Ralph David Scott that, according to the MRI, no fusion surgery had occurred at T9-T10.

94. However, the operative report of Defendant Durrani indicated he in fact, performed surgery from T9-T10 on January 25, 2010.

95. Defendant Durrani's report was not dictated until February 2, 2010, and was not signed until March 12, 2010.

96. Defendant Durrani's other dictating and record keeping practices have been brought into question at Cincinnati Childrens Hospital, Christ Hospital, West Chester Hospital, and these Defendants as well as other medical facilities.

The Improper use of BMP-2 (bone morphogenetic protein)

97. These Defendants also received Medicare payments and/or other consideration for the January 25, 2010 surgery, directly or indirectly, after submitting false, misleading, incorrect claims for payment, including the use of BMP-2 (bone morphogenetic protein) which was improper for the particular surgical application, and that that Ralph David

Scott was warned, informed, and in fact, knowingly consented to the use of BMP-2 on this spinal surgery, which he did not.

98. According to the FDA and independent scientists and physicians, BMP-2 has been causally associated with ectopic bone growth, cancer, spinal stenosis, pain, retrograde ejaculation, throat and breathing constriction, swelling, and other complications.

99. Defendant Durrani also received improper kick backs, consulting fees, and other consideration from the manufacturer of BMP-2, Medtronic, Inc.

100. BMP-2 is marketed by Medtronic as *Infuse* Bone Graft.

101. On July 1, 2008, the FDA issued a Public Health Notification to physicians and medical providers, entitled “Life-threatening Complications Associated with Recombinant Human Bone Morphogenetic Protein in Cervical Spine Fusion [hereinafter the “FDA Warning”].

102. BMP-2 adds substantial cost to already expensive spinal fusion procedures.

103. The January 25, 2010 UC Health billing records for Ralph David Scott indicate the charge for the BMP-2 was additional \$13,219.00, with an additional \$4,625.00 paid to Dr. Durrani.

104. The total facility and surgical charge of the January 25, 2010 surgery billed to Medicare was \$137,705.86.

105. The total physician charge of the January 25, 2010 surgery remains unknown, and further investigation is necessary.

106. The FDA has not approved, and has warned against, the use of BMP-2 for the January 25, 2010 surgery that Defendants performed and received payment and/or other consideration.

107. Defendants knowingly used and were compensated for using BMP-2 on Ralph David Scott on January 25, 2010.

108. The FDA had previously warned Defendants that BMP-2 should not be used as it was by Defendants on January 25, 2010.

109. Defendants improperly used and were paid for the use of BMP-2 on Ralph David Scott during the surgery on January 25, 2010. This surgery violated the FDA warning, and was performed without consent, and without warning.

110. Furthermore, September 8, 2010, Defendant Durrani, acting during the course and scope of his employment with Defendant CAST, performed unnecessary, improper, and/or unsafe surgery on Ralph David Scott at Defendant facilities UC Health and Westchester Hospital. These Defendants received payments and/or other consideration, directly or indirectly, from Medicare after submitting false claims for payment, including facts that the use of BMP-2 (bone morphogenetic protein) for this surgery was approved and proper, and that that Ralph David Scott was informed, and in fact, knowingly consented to the use of BMP-2 on this spinal surgery, which he did not.

111. The September 8, 2010 UC Health billing records for Ralph David Scott have not been produced.

112. The total charges of the September 8, 2010 surgery billed to Medicare remain unknown, and further investigation is necessary.

113. The Federal Drug Administration has not approved, and has warned against, the use of BMP-2 for the September 8, 2010 surgery that Defendants performed and received payment and/or other consideration.

114. The surgery on September 8, 2010 was an anterior cervical fusion.

115. The FDA Warning states *“This is to alert you to reports of life-threatening complications associated with recombinant human Bone Morphogenetic Protein (rhBMP) when used in the cervical spine. Note that the safety and effectiveness of rhBMP in the cervical spine have not been demonstrated and these products are not approved by FDA for this use.”*

116. Defendants knowingly used and were compensated for using BMP-2 on Ralph David Scott on September 8, 2010.

117. The FDA had previously warned Defendants that BMP-2 should not be used as it was in the thoracic spine by Defendants on September 8, 2010.

118. Defendants improperly used and were paid for the use of BMP-2 on Ralph David Scott during the surgery on September 8, 2010. This surgery violated the FDA warning, and was performed without consent, and without warning.

119. Furthermore, on December 6, 2010, Defendant Durrani, acting during the course and scope of his employment with Defendant CAST, performed unnecessary, improper, and/or unsafe surgery on Ralph David Scott at Defendant facilities UC Health and Westchester Hospital. These Defendants received payments and/or other consideration, directly or indirectly, from Medicare after submitting false claims for payment, including facts that the use of BMP-2 (bone morphogenetic protein) for this surgery was approved and proper, and that that Ralph David Scott was informed, and in fact, knowingly consented to the use of BMP-2 on this spinal surgery, which he did not.

120. The December 6, 2010 UC Health billing records for Ralph David Scott have not been produced.

121. The total charges of the December 6, 2010 surgery billed to Medicare remain unknown, and further investigation is necessary.

122. The Federal Drug Administration has not approved, and has warned against, the use of BMP-2 for the December 6, 2010 surgery that Defendants performed and received payment and/or other consideration.

123. Defendants knowingly used and were compensated for using BMP-2 on Ralph David Scott at L4-L5 on December 6, 2010.

124. The FDA had previously warned Defendants that BMP-2 should not be used as it was without patient consent by Defendants on December 6, 2010.

125. Defendants improperly used and were paid for the use of BMP-2 on Ralph David Scott during the surgery on December 6, 2010. This surgery violated the FDA warning, and was performed without consent, and without warning.

126. Furthermore, on September 9, 2011, Defendant Durrani, acting during the course and scope of his employment with Defendant CAST, performed unnecessary, improper, and/or unsafe surgery on Ralph David Scott at Defendant facilities UC Health and Westchester Hospital. These Defendants received payments and/or other consideration, directly or indirectly, from Medicare after submitting false claims for payment, including facts that the use of BMP-2 (bone morphogenetic protein) for this surgery was approved and proper, and that that Ralph David Scott was informed, and in fact, knowingly consented to the use of BMP-2 on this spinal surgery, which he did not.

127. The September 9, 2011 UC Health billing records for Ralph David Scott have not been produced.

128. The total charges of the September 9, 2011 surgery billed to Medicare remain unknown, and further investigation is necessary.

129. The Federal Drug Administration has not approved, and has warned against, the use of BMP-2 for the September 9, 2011 surgery that Defendants performed and received payment and/or other consideration.

130. The surgery on September 9, 2011 involved C1-C2.

131. Defendants knowingly used and were compensated for using BMP-2 on Ralph David Scott at C1-C2 on September 9, 2011.

132. The FDA had previously warned Defendants that BMP-2 should not be used as it was by Defendants on September 9, 2011.

133. Defendants improperly used and were paid for the use of BMP-2 on Ralph David Scott during the surgery on September 9, 2011. This surgery violated the FDA warning, and was performed without consent, and without warning.

134. The FDA Warning was specifically directed to medical providers and facilities, including Defendants, who were using BMP-2 without FDA approval, also called “off label” use.

135. The FDA Warning cautioned that “[t]he mechanism of action [of BMP-2] is unknown, and characteristics of patients at increased risk have not been identified.”

136. Subsequent to these Defendants’ off label use of BMP-2, Ralph David Scott has suffered breathing difficulties, sexual dysfunction, increased pain, swelling, stiffness, slow wound healing, mental status changes, anxiety, and fear.

137. Ralph David Scott complained of these resulting symptoms to Defendant Durrani, but Defendant Durrani refused, even after the fact, to inform Plaintiff of the use of BMP-2 and risks associated therewith.

138. The “*FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices.*”

139. Defendants failed to report the improper uses; caused physical injuries; and received improper compensation for using BMP-2; which acts and omissions, alone or in combination, were the proximate cause of the resulting serious injuries and financial damages as alleged in this Complaint.

140. The United States Government, the Commonwealth of Kentucky, the State of Ohio and the public interest have been damaged as a result of Defendants violations of the False Claims Act.

141. Plaintiff have sustained injury to their business or property including out-of-pocket financial losses, lost co-payments and deductibles, lost wages, lost economic opportunities, and lost fringe benefits all by reason of Defendants identified pattern of racketeering activity.

142. The attached Exhibit A is a detailed specific example of facts supporting Civil Rico.

143. The attached Exhibit B are lawsuits filed supporting Civil Rico.

144. The attached Exhibit C are narratives to support Civil Rico.

145. Plaintiffs request a jury trial on all issues so triable.

WHEREFORE, Plaintiffs request that this court enter judgment against Defendants all commentary, punitive and treble damages allowed and all attorney fees and costs.

PLAINTIFFS DEMAND A TRIAL BY JURY.

Respectfully submitted,

\s\Eric C. Deters

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